

EU Declaration of Conformity

Manufacturer: SHENGZHEN FINICARE CO., LTD.
201, No. 50, the 3rd Industrial Park, Houting Community, Shajing
Street, Bao'an District, 518104 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA
SRN: CN-MF-000024364

European Representative: RIOMAVIX SOCIEDAD LIMITADA
Calle de Almansa 55, 1D, Madrid, 28039 Spain
SRN: ES-AR-000001202

Product Name: Infrared Thermometer
Model: FC-IR100, FC-IR300, FC-IR400, FC-IR105, FC-IR1030, FC-
IR3010, FC-IR2000, FC-IR205, FC-IR202, FC-IR101, FC-IR200,
FC-IR206, FC-IR207, FC-IR109
EMDN Code: V03010102
Basic UDI-DI: See attachment 1.

Intended purpose of device: The Infrared Thermometer is intended for the measurement of human body temperatures in the home setting and medical institutes.

Classification (MDR, Annex VIII): Class IIa, Rule 10.

Conformity Assessment Route: Annex IX Chapter I & III of Regulation (EU) 2017/745.

We herewith declare that the above-mentioned products meet the provisions of the MDR (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

SHENGZHEN FINICARE CO., LTD. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidances:

ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, IEC 60601-1:2005+A1:2012, EN 60601-1-2:2015, EN ISO 80601-2-56:2017+A1:2018, IEC 60601-1-11:2015+A1:2021, IEC 62304:2006+A1:2015, EN 62366-1-2015+AC:2015, EN 60601-1-6:2010+A1:2015, EN ISO 14971:2019, ISO/TR 24971:2020, ETSI EN 300 328 V2.2.2(2019-07), EN 62479:2010, EN 50663:2017, ETSI EN 301 489-1 V2.2.3(2019-11), ETSI EN 301 489-17 V3.2.4(2020-09), ASTM D4169-2016, MEDDEV. 2.7.1 Rev.4.

Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339 München, Germany

NB Identification number: 0123
(EC) Certificate(s): No. G10 004665 0011 Rev. 00
Expire date of the Certificate: 2028-10-16
Start of CE Marking: 2023-10-17
Signature: Chao Li
Name: Chao Li
Position: General Manager
Place/date: Shenzhen City, 2023-10-18

Attachment 1. Product Basic UDI-DI information:

Models	Basic UDI-DI
FC-IR100, FC-IR300,FC-IR400,FC-IR105, FC-IR1030,FC-IR3010	697152282IR001D3
FC-IR2000, FC-IR205, FC-IR202, FC-IR101, FC-IR200,FC-IR206, FC-IR207	697152282IR002D5
FC-IR109	697152282IR003D7